

Patent Appln. No. 10/648,408
Atty. Docket No. PC 23296A

REMARKS

Initially, Applicants thank the Examiner for indicating that there are no art-based rejections, that claim 2 would be allowable in independent form, and for returning initialed and signed copies of Applicants' information disclosure citations.

Status of the Claims

Claims 1-20 were originally pending. In the Office Action mailed 22 July 2005, claims 1 and 3-20 are rejected as being nonenabled and claim 2 is objected to as depending from a rejected claim. By this Amendment, claims 1-20 are canceled without prejudice or disclaimer and replaced with new claims 21-33.

Response to Enablement Rejection

Claims 1 and 3-20 are rejected under 35 USC § 112, ¶ 1, as lacking enablement in that solvate forms of the claimed compounds are allegedly not enabled. In particular, it is stated that the specification proves that the claimed compounds do not and cannot exist as solvates. This conclusion is evidently based on an assertion that solvates would have necessarily formed according to Applicants' disclosed procedures, and thus, that the absence of specific solvate examples in the specification proves that solvate forms cannot exist. Applicants respectfully traverse the rejection.

Primarily, Applicants respectfully submit that the rejection does not shift to Applicants the burden of demonstrating enablement. See *In re Marzocchi*, 439 F.2d 220, 222 (CCPA 1971) (burden is on the Patent Office to prove nonenablement). The rejection cites only a lack of actual solvate examples as allegedly proving that the claimed compounds do not form solvates. Respectfully, Applicants suggest that the theory that solvates necessarily "would have formed" according to the disclosure is incorrect and inevitably led to an erroneous conclusion that solvate forms of the claimed compound do not and cannot exist. Actually, solvates can be formed according to ordinary skill in the art, such as in a standard solvate screen, even where solvates do not spontaneously form, e.g., upon recrystallization. Thus, consistent with the general rule, there should be no *per se* requirement for examples or disclosure of each and every claimed embodiment in the present case. Thus, the rejection respectfully lacks any affirmative evidence of non-enablement.

As noted, the enablement standard does not require an applicant to disclose that which would be understood by the skilled artisan or obtainable without undue experimentation, and does not contain a requirement for examples. In this case, the skilled artisan would not expect potential solvate formation to necessarily be spontaneous, and would not expect the lack thereof to be determinative of the accessibility of solvates, and

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thus would not read a lack of solvate examples as indicating that solvates would not form. To the contrary, because solvate formation is a standard practice, the skilled artisan would reasonably (and correctly) expect that solvates could form and could actually obtain them without undue experimentation. This is especially true given the relatively narrow scope of the compound genus for which solvate forms thereof are presently claimed. In fact, as a result of significant interest in the claimed compounds, a standard polymorph screen of one of the compounds was carried out and resulted in several different solvate forms thereof. It would be unreasonable for the Patent Office to require disclosure of such screening results that are performed according to ordinary skill in the art.

Finally, the rejection invites Applicants to show that solvates can be made. In response, Applicants respectfully submit that a showing that something *can in fact* be made would not without further explanation in and of itself necessarily be dispositive of the appropriate standard of enablement by an application. Nonetheless, as noted above, solvates of the claimed compound have been prepared.

Conclusion

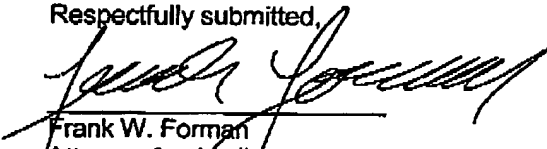
In view of the above, Applicants respectfully submit that all of the pending claims are enabled and allowable in their present form, and that the application is otherwise in condition for allowance. The Examiner is respectfully requested to withdraw the rejection and, as the next official action, to provide a Notice of Allowance.

If any issues remain which can be resolved by a telephone conference, or should the Examiner have any questions or comments regarding this matter, the Examiner is respectfully invited to contact the undersigned at the telephone number shown below.

Date:

21 Oct 05

Respectfully submitted,


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